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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,655	12/29/2004	Richard Farrar	6320-75538	5124
23643 7590 12/21/2007 BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204			EXAMINER COZART, JERMIE E	
			ART UNIT 3726	PAPER NUMBER
			MAIL DATE 12/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,655

Applicant(s)

FARRAR, RICHARD

Examiner

Jermie Cozart

Art Unit

3726

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/04; 1/24/05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.
2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 6, 7, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6, *lines 1-3*, it is unclear as to what is meant by "the portion of the bearing surface which is defined by the cutting tool between any pair of consecutive incremental movements thereof extends through an angle of arc of at least about 1°". It is also unclear as to how this portion is defined by the cutting tool. In claim 7, *lines 1-3*, it is unclear as to how "the portion of the bearing surface which is defined by the cutting tool between any pair of consecutive incremental movements thereof extends through an angle of arc of not more than about 20°". It is also unclear as to how this portion is defined by the cutting tool. In claim 9, *lines 1-3*, it is unclear as to what is meant by "the portion of the bearing surface over which the radius of curvature is approximately constant extends over a cone half angle of at least about 10°". Appropriate correction is required.
5. Claim 4 recites the limitation "it" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Semlitsch (6,126,695).

Regarding claim 1, Semlitsch discloses method of making a component of an orthopedic joint prosthesis which has a bearing surface (A) whose shape corresponds approximately to a part of a sphere and is symmetrical about its polar axis, wherein a cutting tool (17) is used which has a circular cutting edge (17A) and which can be rotated about an axis which is perpendicular to the plane containing the cutting edge by rotating the component (1) about its polar axis (14) and rotating the cutting tool (17) about its axis (16), with the cutting edge of the cutting tool in contact with the surface of the component (1), and moving the cutting tool (17) in a direction parallel to the polar axis (14) of the component (1) while leaving the angle between the axis (16) of the cutting tool (17) and the polar axis of the component (1) unchanged, and along its axis. It is apparent that these steps are repeated. The movements (col. 5, lines 49-67) of the cutting tool (17) causing the radius of curvature of the bearing surface to change continuously and monotonically as the angle between the radius and the polar axis of the component changes, so that the shape of the bearing surface (A) deviates from that of a true sphere in such a way that discontinuities in the shape of the bearing surface as a result of individual movements are minimized.

Regarding claim 2, Semlitsch discloses the cutting tool (17) being moved along its axis in a direction (col. 5, lines 49-67) towards the bearing surface of the component,

as the cutting tool (17) is moved along the polar axis in a direction away from the bearing surface (A) of the component.

Regarding claim 3, Semlitsch discloses the bearing surface (A) of the component being concave (see Fig. 5).

Regarding claim 5, Semlitsch discloses the inherent simultaneous movements (col. 5, lines 49-67) of the cutting tool (17) along its axis, and in a direction parallel to the polar axis of the component, are performed in incremental steps.

Regarding claim 8, Semlitsch discloses the bearing surface (A) of the finished component includes a portion at and around the pole over which the radius of curvature is approximately constant.

Regarding claim 10, it is inherent that the component (1) is sterilized so that it is suitable for implantation in a human or animal body as a component of an orthopedic joint prosthesis.

See column 5, line 44 - column 6, line 9 and figure 3 for further clarification.

8. Claims 1-3, 5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagenseil (5,823,721).

Regarding claim 1, Wagenseil discloses method of making a component which has a bearing surface (2) whose shape corresponds approximately to a part of a sphere and is symmetrical about its polar axis, wherein a cutting tool (14) is used which has a circular cutting edge (16) and which can be rotated about an axis (13) which is perpendicular to the plane containing the cutting edge by rotating the component (1) about its polar axis (V) and rotating the cutting tool (14) about its axis (), with the cutting

edge of the cutting tool in contact with the surface of the component (1), and moving the cutting tool (14) in a direction parallel to the polar axis (V) of the component (1) while leaving the angle between the axis (13) of the cutting tool (14) and the polar axis of the component (1) unchanged, and along its axis. It is apparent that these steps are repeated. The movements (col. 3, line 63 - column 4, line 53) of the cutting tool (14) causing the radius of curvature of the bearing surface to change continuously and monotonically as the angle between the radius and the polar axis of the component changes, so that the shape of the bearing surface (2) deviates from that of a true sphere in such a way that discontinuities in the shape of the bearing surface (2) as a result of individual movements are minimized.

Note that the recitation "of an orthopedic joint" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Regarding claim 2, Wagenseil discloses the cutting tool (14) being moved along its axis in a direction towards the bearing surface (2) of the component (1), as the cutting tool (14) is moved along the polar axis in a direction away from the bearing surface of the component.

Regarding claim 3, Wagenseil discloses the bearing surface of the component () being concave.

Regarding claim 5, Wagenseil discloses the simultaneous movements (col. 4, lines 13 - 40) of the cutting tool along its axis, and in a direction parallel to the polar axis of the component, are performed in incremental steps.

Regarding claim 8, Wagenseil discloses the bearing surface of the finished component (1) includes a portion at and around the pole over which the radius of curvature is approximately constant (see the Figure).

See column 3, line 7 – column 4, line 60 and the Figure for further clarification.

9. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (3,212,405).

Regarding claim 1, Smith discloses method of making a component which has a bearing surface (28) whose shape corresponds approximately to a part of a sphere and is symmetrical about its polar axis, wherein a cutting tool (24) is used which has a circular cutting edge (26) and which can be rotated about an axis which is perpendicular to the plane containing the cutting edge by rotating the component (14) about its polar axis (16) and rotating the cutting tool (24) about its axis (22), with the cutting edge of the cutting tool in contact with the surface of the component (14), and moving the cutting tool (24) in a direction parallel to the polar axis (16) of the component (14) while leaving the angle between the axis (22) of the cutting tool (24) and the polar axis of the component (14) unchanged, and along its axis. It is apparent that these steps are repeated. The movements (col. 2, lines 13 - 47) of the cutting tool (24) causing the

radius of curvature of the bearing surface to change continuously and monotonically as the angle between the radius and the polar axis of the component changes, so that the shape of the bearing surface (28) deviates from that of a true sphere in such a way that discontinuities in the shape of the bearing surface as a result of individual movements are minimized.

Note that the recitation "of an orthopedic joint" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Regarding **claim 2**, Smith discloses the cutting tool (24) being moved (col. 2, lines 21 - 47) along its axis in a direction towards the bearing surface of the component, as the cutting tool (24) is moved along the polar axis in a direction away from the bearing surface of the component.

Regarding **claim 3**, Smith discloses the bearing surface of the component (14) being concave (see Fig. 1).

Regarding **claim 8**, Smith discloses the bearing surface of the finished component (14) including a portion at and around the pole over which the radius of curvature is approximately constant.

See column 2, lines 13 – 63 and figures 1-2 for further clarification.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Semlitsch (6,126,695), Wagenseil (5,823,721), or Smith (3,212,405).

Regarding **claim 4**, Semlitsch, Wagenseil, or Smith each disclose their respective cutting tools being annular such that each cutting tool has a circular cutting edge which can be applied against the bearing surface, however, each fails to disclose the bearing surface of the component being convex or wherein the circular cutting edge can be applied against the convex bearing surface.

The structural limitation "the bearing surface of the component being convex" has not been given patentable weight since it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not amount to the mere claiming of a use of a particular structure (i.e. bearing surface of component being convex). *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

Each of the references above does not disclose expressly the bearing surface of the component being convex.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have formed the bearing surface

of the components of Semlitsch, Wagenseil, or Smith as being convex because Applicant has not disclosed that provide the bearing surface of the component as convex provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the bearing surface of the component being concave because the concave bearing surface provides the necessary contoured features.

Therefore, it would have been an obvious matter of design choice to modify Semlitsch, Wagenseil, or Smith to obtain the invention as specified in claim 4.

12. Claims 6, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Semlitsch (6,126,695) or Wagenseil (5,823,721).

Both Semlitsch and Wagenseil each disclose the claimed invention except for the following: the portion of the bearing surface which is defined by the cutting tool between any pair of consecutive incremental movements extending through an angle of arc of at least 1°; the portion of the bearing surface which is defined by the cutting tool between any pair of consecutive incremental movements extending through an angle of arc not more than about 20°; or the radius of curvature approximately constantly extends over a cone half angle of at least about 10°.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the portion of the bearing surface of Semlitsch and Wagenseil which is defined by the cutting tool between any pair of consecutive incremental movements extend through an angle of arc of at least 1° and not more than

about 20°, and to make the radius of curvature of the bearing surface of Semlitsch and Wagenseil approximately constantly extend over a cone half angle of at least about 10°, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The reference cited on the attached PTO-892 is cited to show the production of a contoured bearing surface.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.


15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JERMIE E. COZART
PRIMARY EXAMINER

December 16, 2007